Cancer Therapy Evaluation Program
Division of Cancer Treatment & Diagnosis

9609 Medical Center Drive; Room 5W228;
MSC 9725; Rockville, MD 20850

P (240) 276-6575

Email:PMBafterhours@mail.nih.gov

INSIDE PMB

February 2015

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Contact Information

Investigator Brochures for which CTEP holds IND:

ibcoordinator@mail.nih.gov

Investigator registration questions:

pmbregpend@ctep.nci.nih.gov

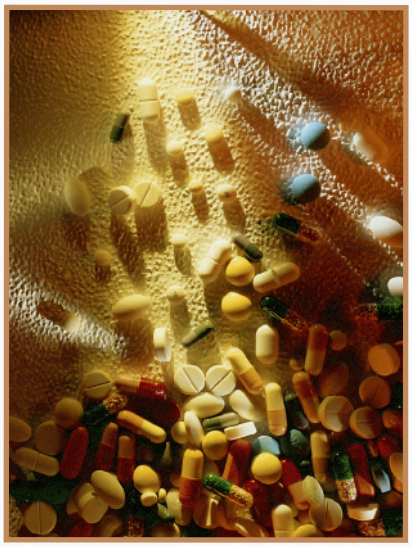
Questions about IAM account establishment process:

CTEPREGHelp@ctep.nci.nih.gov

U.S. Department of Health and Human Services
National Institutes of Health
National Cancer Institute

Authorized Prescribers:

Rostered vs. Non-Rostered



The answer to the question which investigator is authorized to prescribe the CTEP IND agent has always been a challenge for pharmacists and those who are responsible to fill prescription. As if that is not challenging enough, now, there are new terms, ***rostered*** *and* ***non-rostered*** that are being routinely used when referring to the NCI participants and the PI registration. We use these terms frequently. Here an explanation to get you on board.

To prescribe NCI-supplied IND agent, investigators must:

- Have an active CTEP investigator registration
- Be eligible to participate on the trial

Determining investigator eligibility for trial participation:

For *Rostered* participant protocol (e.g., NCTN Groups, Lead Academic Organizations, Phase 2 Consortiums) – the investigator must have a current active organizational affiliation with one of the rostered organizations identified as participants on the title page of the protocol.

For Non-*Rostered* participant protocols (e.g., single center or multi-centered studies) – the investigator and the investigator's institution must be identified as participants on the title page of the protocol.

Both investigator registration status and investigator organizational affiliations can be verified on the PMB website at: http://ctep.cancer.gov/branches/pmb/expiration_date.htm. Both the CTEP investigator ID number and last name are required.

Further information regarding this topic will be made available in the upcoming Investigational Drug Accountability Training video "Agent Dispensing" which will be available at: http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm

No more free-texting in the query field!

Update to Stock Notification Letters in OAOP

You may have noticed a minor change in the Standard Order Stock Notification query on the OAOP website. “Free-texting” of agent or component lot numbers into the fields is no longer possible. When querying for stock notification letters for specific lots, the agent NSC number or agent name or component name must be selected first. Once the agent or component is selected, users must select the lot number from the lot number field list of values. This change was implemented to prevent erroneous entry into the lot number fields.

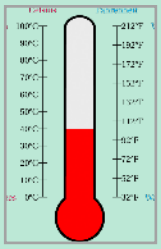
Select the agent NSC number or agent name or component name

Select the lot number from the lot number field list of values

Temperature Excursion

The refrigerator or the air conditioning is broken. Your patient is scheduled to receive the clinical supply this week. What should you do? First, you need to quarantine the clinical supply, and then contact PMB for guidance on the suitability of the clinical supply.

1. If you need an immediate answer, call PMB at 240-276-6575.
2. If you don’t need an immediate response, send an email to PMBAfterhours@mail.nih.gov including a detail report of the temperature excursion and data.



The clinical supplies that are determined not suitable for clinical use must be returned to the NCI Clinical Repository, at the address below, accompanied by a completed Return Drug List (NIH-986).

627 Lofstrand Lane
Rockville, MD 20850
Attention: RETURNS

Is using the overfill volume to complete the calculated dose acceptable instead of using another vial?

Overfill Volume

You’ve withdrawn the calculated dose volume from the agent vial but need 0.1 mL to complete the dose. You realize that the vial contains an overfill and would like to use the remaining volume.

Q. Should you use the remaining volume?

A. Absolutely! And don’t forget to document the use of overfill on the DARF.

Also, be aware that reconstituting lyophilized powder vials may result in an overfill due to the dead space volume that is being compensated. Ensure that you follow the preparation guidelines accordingly.

Our FAQ on that matter can be accessed via http://ctep.cancer.gov/branches/pmb/faq/docs/injectable_agents_in_vials.pdf

IDS Pharmacy Check List

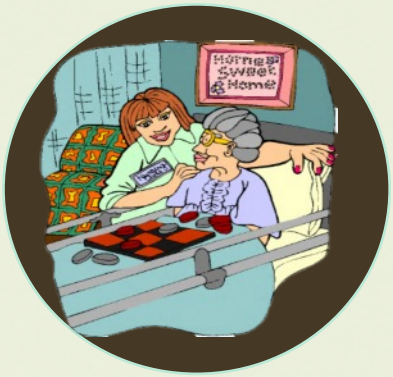
A few items to consider as a check list before you process an order written for an investigational agent.

"The principal investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol."

GCP guidelines

1. Verify that you have the most up-to-date version of the protocol.
2. Verify that the investigator(s) registration is current; i.e., his/her registration status is active. Also, the investigator(s) is authorized to write the prescription.
3. Ensure that you have the agent supply available for that particular study including the dosage strength(s)
5. Ensure that staff responsible for preparing and dispensing the agent(s) have completed the training module for that study.

Information about NCI agent dispensing will be available in the NCI/PMB YouTube training module 5. T**he tutorial training module 5, Agent Dispensing** will be live shortly. We will keep you posted!



Repackaging

Most of you ask this - Is it acceptable to repackage the CTEP IND agent in a pharmacy dispensing bottle ?

The answer is, "It depends."

If the protocol recommends to "dispense it in its original container," then you cannot repackage capsules/tablets in container other than the original bottle.

Some protocols include an exception to allow repackaging for a short period of time. For example, *agent X* is permitted to be dispensed in a dispensing pharmacy container for up to 7 days. Anything beyond the permitted storage duration of 7 days must be dispensed in its original bottle.

Some sites' SOP require dispensing the exact quantity of capsules/tablets to patients according to the patient's treatment plan. Please check with us before you remove extra capsules/tablets from the original bottles.

If the protocol does not have any guidance, please call PMB.

Is removing extra caps/tabs from original bottle acceptable?

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